UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 08/965,356 | 11/06/97 | BERNFIELD M | CMCC533 |

HM22/0815
PATREA L PABST
ARNOALL GOLDEN & GREGORY LLP
2800 ONE ATLANTIC CENTER
1201 WEST PEACHTREET STREET
ATLANTA GA 30309-3450

| EXAMINER | |
|---|---|
| BAKER, A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | 25 |
| **DATE MAILED:** | 08/15/00 |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Advisory Action

| Application No. | Applicant(s) |
|---|---|
| 08/965,356 | Bernfield et al. |
| **Examiner** | **Group Art Unit** |
| Anne-Marie Baker, Ph.D. | 1632 |

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☐ expires _____ months from the mailing date of the final rejection.

b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☒ Appellant's Brief is due two months from the date of the Notice of Appeal filed on *Jul 6, 2000* (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

**Applicant's response to the final rejection, filed on *Jun 8, 2000* has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☐ The proposed amendment(s):

- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☐ will not be entered because:
  - ☐ they raise new issues that would require further consideration and/or search. (See note below).
  - ☐ they raise the issue of new matter. (See note below).
  - ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s):

_____

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
*Although Applicants have cited one example where transgene expression leads to the same phenotype in both rats and mice (growth hormone transgenics), one skilled in the art would not expect that such a result could be (see attached)*

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: *1, 3-6, 10, and 12-15 stand rejected for reasons of record.*

☐ The proposed drawing correction filed on _____ ☐has ☐has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

☐ Other

**Advisory Action**

(cont.) routinely obtained for all transgenic animals or even all transgenic rodents. Undue experimentation would have been required to produce syndecan transgenic rats or rodents other than mice because the generation of a desired phenotype in a transgenic animal of a particular species is not routinely successful even after a transgenic animal of another species has been shown to exhibit said desired phenotype. Examples in support of this conclusion have already been cited (Paper Nos. 8, 13, and 21). These examples show that studies in mice are not predictive of the same results in rats. Importantly, the level and location of transgene expression is critical to the development of the phenotype. The instant specification does not disclose the level of syndecan expression that would be required in a rat or other rodent to produce a phenotype of maturity onset obesity. Therefore, the level of expression sufficient to produce the desired phenotype in a rat or other rodent is not known. Undue experimentation would have been required for one skilled in the art to determine the level of expression required and to design appropriate transgene constructs that would produce the required level of product in the appropriate tissue. Thus, although the growth hormone transgenic rats and mice exhibited the same phenotype, transgene constructs designed for mice are not routinely applied to the development of other transgenic rodents with the same results. The level and location of transgene expression are crucial to the development of the phenotype. In the instant case, the skilled artisan would not know how to produce a level of expression sufficient to produce the desired phenotype or even if the desired phenotype can be produced at any level of expression. The state of the art renders it unpredictable as to whether one skilled in the art could produce a transgenic rat or other rodent (with the exception of mice) expressing a sufficient amount of any syndecan to produce an obese phenotype. Thus, undue experimentation would have been required to produce the claimed transgenic rodents.

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER